

**UNITED STATES DISTRICT COURT FOR THE  
WESTERN DISTRICT OF NORTH CAROLINA  
CHARLOTTE DIVISION  
3:11-cv-344-RJC-DSC**

**VINCENT KOEHLER,** )  
 )  
 **Plaintiff,** )  
 )  
 v. )  
 )  
 **RITE-AID PHARMACY and KV** )  
 **PHARMACEUTICALS,** )  
 )  
 **Defendant,** )  
 )  
 **U.S. FOOD AND DRUG** )  
 **ADMINISTRATION** )  
 )  
 **Guarantor.** )  
 )

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**ORDER**

**THIS MATTER** comes before the Court on Defendants Eckerd Corporation (“Eckerd”) and K-V Pharmaceutical Company’s (“KV,” collectively with Eckerd “Corporate Defendants”)<sup>1</sup> joint Motion to Dismiss, (Doc. No. 8), the United States Food and Drug Administration’s (“FDA”) Motion to Dismiss for Lack of Subject Matter Jurisdiction, (Doc. No. 12), the Magistrate Judge’s Memorandum and Recommendation (“M&R”), recommending that the Court grant both motions, (Doc. No. 18), and Plaintiff Vincent Koehler’s (“Plaintiff”) Objections, (Doc. No. 21), and Motion for Summary Judgment, (Doc. No. 20).

**I. STANDARD OF REVIEW**

The district court has authority to assign dispositive pretrial matters pending before the court to a magistrate judge for “proposed findings of fact and recommendations.” 28 U.S.C. §

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<sup>1</sup> Eckerd contends that Plaintiff misnamed it as “Rite-Aid Pharmacy” and represents to the Court that Eckerd is a wholly owned subsidiary of Rite Aid Corporation. (Doc. No. 9 at 1, 1 n.1). KV contends that Plaintiff misnamed it as “KV Pharmaceuticals” and represents to the Court that its proper name is K-V Pharmaceutical Company. (*Id.*).

636(b)(1)(B). The Federal Magistrate Act provides that “a district court shall make a de novo determination of those portions of the report or specific proposed findings or recommendations to which objection is made.” Id. at § 636(b)(1); Camby v. Davis, 718 F.2d 198, 200 (4th Cir. 1983). De novo review is not required by the statute “when a party makes general or conclusory objections that do not direct the court to a specific error in the magistrate judge’s proposed findings and recommendations.” Id.

In its review of a Rule 12(b)(6) motion, “the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff.” Mylan Labs, Inc. v. Matakari, 7 F.3d 1130, 1134 (4th Cir. 1993). The plaintiff’s “[f]actual allegations must be enough to raise a right to relief above the speculative level.” Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). “[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint.” Id. at 563. A complaint attacked by a Rule 12(b)(6) motion to dismiss will survive if it contains “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (quoting Twombly, 550 U.S. at 570). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Id.

## **II. BACKGROUND**

On June 17, 2011, Plaintiff filed a complaint against the Corporate Defendants and the FDA in Mecklenburg County Superior Court. (Doc. No. 1-1). Plaintiff alleges that he “got very ill with severe nausea and vomiting during the last week of May 2008,” after ingesting KV’s Morphine Sulfate Extended Release product. (Id. at 1-2 & 6). Plaintiff filled his prescription for this drug at an Eckerd pharmacy. (Id. at 1). While Plaintiff promptly sought medical attention,

none of his doctors could diagnose the source of his injuries until Plaintiff received a drug recall notice from the Corporate Defendants on June 20, 2008. (Id. at 1-2).

On July 2, 2008, Plaintiff alerted the FDA to his difficulties with KV's drug through the filing of a "FORM FDA 3500." (Id. at 10). In this filing, Plaintiff detailed his ingestion of the drug followed by his injuries, but did not make any claim for damages from the government. (Id.). The FDA responded by letter dated July 16, 2008. (Id. at 11). The FDA thanked Plaintiff for bringing his difficulties to the FDA's attention and informed him that his report had been added to a "postmarketing safety database" that may result in regulatory actions that improve safety. (Id.).

The FDA removed this case to federal court on July 15, 2011, citing 28 U.S.C. § 1442(a)(1) as supporting this Court's jurisdiction. (Doc. No. 1). Section 1442(a)(1) permits any United States agency sued in state court for any official act to remove the case to federal court. 28 U.S.C. § 1442(a)(1). All defendants now move to dismiss. (Doc. Nos. 8; 12). The Magistrate Judge found that "Plaintiff's claims are barred by the applicable statute of limitations" and that the Corporate Defendants' motion should be granted on that basis. (Doc. No. 18 at 2). With respect to the FDA's motion, the Magistrate Judge found that because Plaintiff's only allegation against the FDA is that it is a "guarantor" of his claims against the Corporate Defendants, Plaintiff's claims against the FDA must also be dismissed. (Id. at 3). Plaintiff objected to the Magistrate Judge's statute of limitations finding and argued that the FDA must be held responsible. (Doc. No. 21).

### **III. ANALYSIS**

The FDA moved to dismiss this case based on a lack of subject matter jurisdiction. (Doc. No. 12). "The subject matter jurisdiction of federal courts is limited and the federal courts may

exercise only that jurisdiction which Congress has prescribed.” Chris v. Tenet, 221 F.3d 648, 655 (4th Cir. 2000). In removing this case to federal court the FDA relied upon 28 U.S.C. § 1442(a)(1), which permits any United States agency sued in state court for any official act to remove the case to federal court. (Doc. No. 1). The Fourth Circuit has held that:

It is clear that a federal court's jurisdiction upon removal under 28 U.S.C. § 1442(a)(1) is derivative of the state court jurisdiction, and where the state court lacks jurisdiction over the subject matter or the parties, the federal court acquires none upon removal, even though in a like suit originally brought in federal court, the court would have had jurisdiction. It is also clear that an action seeking specific relief against a federal official, acting within the scope of his delegated authority, is an action against the United States, subject to the governmental privilege of sovereign immunity. Where an agency has not waived its immunity to suit, the state court (and the federal court on removal) lacks jurisdiction to proceed against a federal employee acting pursuant to agency direction.

Smith v. Cromer, 159 F.3d 875, 879 (4th Cir. 1998) (citing Boron Oil Co. v. Downie, 873 F.2d 67, 69 (4th Cir. 1989)) (internal citations omitted). The United States has waived its sovereign immunity for claims arising out of torts committed by federal employees through the Federal Tort Claims Act, 28 U.S.C. § 1346(b)(1) (“FTCA”). But this waiver requires strict adherence to the terms of the FTCA. While Plaintiff does not reference the FTCA, it is “the sole potential remedy for tortious injury that [he] may pursue against the federal government under these circumstances.” Megna v. Food & Drug Admin., No. 08-cv-1435, 2009 WL 749900 (E.D.N.Y. Mar. 17, 2009). “The FTCA bars claimants from bringing suit in federal court until they have exhausted their administrative remedies.” McNeil v. United States, 508 U.S. 106, 113 (1993). Specifically, the FTCA bars tort claims against the United States unless the plaintiff presents his claim to the appropriate federal agency within two years after the claim accrues. See 28 U.S.C. §§ 2401(b); 2675(a).

Plaintiff has failed to exhaust his remedies as required by the FTCA. As a result, this

Court lacks subject matter jurisdiction over the FDA. Plaintiff did file a “FORM FDA 3500” on July 2, 2008. (Doc. No. 1-1 at 10). But Plaintiff failed to make any claim against the FDA in this form. Plaintiff has not alleged that he filed any other claim against the government. See also Grant v. Sec’y, U.S. Dep’t of Veterans Affairs, No. 03-5260, 2004 WL 287125, at \*1 (D.C. Cir. Feb. 4, 2004) (requiring claim for a sum certain to be made on agency). The FDA’s Motion to Dismiss for Lack of Subject Matter Jurisdiction, (Doc. No. 12), is **GRANTED**.

The FDA recommends that the Court remand this action in the event it dismisses the FDA from the suit. (Doc. No. 13). 28 U.S.C. § 1447(c) requires the Court to remand if it appears that the Court lacks subject matter jurisdiction at any time before final judgment. The FDA removed this action, relying on 28 U.S.C. § 1442(a)(1) for jurisdiction. (Doc. No. 1). Without a federal agency in the action, that section no longer supplies the Court jurisdiction. 28 U.S.C. § 1442(a)(1). No party has alleged an alternative basis for the Court’s jurisdiction and the Corporate Defendants neither joined nor consented to the FDA’s removal, (Doc. No. 1). “The burden of persuasion for establishing diversity jurisdiction, of course, remains on the party asserting it.” Hertz Corp. v. Friend, 130 S. Ct. 1181, 1194 (2010). Here, no remaining party has asserted it.

28 U.S.C. § 1367(a) provides the Court supplemental jurisdiction over Plaintiff’s claims against the Corporate Defendants because they “are so related” to Plaintiff’s claims against the FDA “that they form part of the same case or controversy.” 28 U.S.C. § 1367(a). But once a district court has dismissed all claims over which it had original jurisdiction, it may decline to exercise supplemental jurisdiction over a supplemental claim. Id. at § 1367(c). The Court has “wide discretion” in deciding whether to retain jurisdiction over the state claims in such a case. Shanaghan v. Cahill, 58 F.3d 106, 110 (4th Cir. 1995); see also Peter Farrell Supercars, Inc. v.

Monsen, 82 F. App'x 293, 296 (4th Cir. 2003). “Among the factors that inform this discretionary determination are convenience and fairness to the parties, the existence of any underlying issues of federal policy, comity, and considerations of judicial economy.”

Shanaghan, 58 F.3d at 110. But the Fourth Circuit has also held that:

Needless decisions of state law should be avoided both as a matter of comity and to promote justice between the parties, by procuring for them a surer-footed reading of applicable law. Certainly, if the federal claims are dismissed before trial, even though not insubstantial in a jurisdictional sense, the state claims should be dismissed as well.

In re Conklin, 946 F.2d 306, 322 (4th Cir. 1991) (citing United Mine Workers of Am. v. Gibbs, 383 U.S. 715, 725-27 (1966)). The Supreme Court has stressed that while there is no “mandatory rule to be applied inflexibly in all cases,”

in the usual case in which all federal-law claims are eliminated before trial, the balance of factors to be considered under the pendent jurisdiction doctrine—judicial economy, convenience, fairness, and comity—will point toward declining to exercise jurisdiction over the remaining state-law claims.

Carnegie-Mellon Univ. v. Cohill, 484 U.S. 343, 350 (1988).

The Corporate Defendants neither joined nor consented to the FDA’s removal, (Doc. No. 1), and Plaintiff chose Mecklenburg County Superior Court as his desired forum, (Doc. No. 1-1). Thus, the parties appear to prefer state court. The defendants have not yet filed answers in this case and discovery has not yet begun. No party has invoked any issue of federal policy. Remanding the case to state court would “procure[] for them a surer-footed reading” of the applicable statute of limitations, and if appropriate, the substantive law supporting Plaintiff’s claims. This Court has not yet devoted a substantial amount of resources to the resolution of Plaintiff’s case. The balance of these factors weighs in favor of remand. Therefore, the Court **REMANDS** this case to Mecklenburg County Superior Court and **DISMISSES** the Corporate

Defendants' Motion to Dismiss, (Doc. No. 8).

#### IV. CONCLUSION

This Court's jurisdiction was predicated upon the presence of the FDA as a defendant. (Doc. No. 1). But Plaintiff failed to exhaust his remedies as required by the FTCA. As a result, this Court lacks subject matter jurisdiction over the FDA. No party has alleged an alternative basis for the Court's jurisdiction over Plaintiff's claims against the Corporate Defendants. Due to the early stage of this litigation, the balance of convenience factors weighs in favor remanding the remaining pendent state claims to state court.

#### IT IS, THEREFORE, ORDERED THAT:

1. The FDA's Motion to Dismiss for Lack of Subject Matter Jurisdiction, (Doc. No. 12), is **GRANTED**;
2. The Corporate Defendants' Motion to Dismiss, (Doc. No. 8), Plaintiff's Objections, (Doc. No. 21), and Plaintiff's Motion for Summary Judgment, (Doc. No. 20) are **DISMISSED**; and
3. This case is **REMANDED** to Mecklenburg County Superior Court.

Signed: January 11, 2012



Robert J. Conrad, Jr.  
Chief United States District Judge

